A real-world study of Alemtuzumab in a cohort of Italian patients

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Introduction: Real-world data on Alemtuzumab is limited and does not provide evidence on its effectiveness after different Disease Modifying Therapies (DMTs).
Objectives: To evaluate the impact of clinical variables on ARR and No Evidence of Disease Activity (NEDA) during Alemtuzumab therapy.
Aims: To provide real-world data on the efficacy of Alemtuzumab.
Methods: We retrospectively included patients from eighteen Italian MS-centers who started Alemtuzumab, and recorded demographics, previous therapies, washout duration, relapses and EDSS. Negative-binomial regression models were used to assess the effect of factors on ARR after Alemtuzumab initiation.
Results: We included 322 patients (mean age 36.8 years, 71.1% females, median EDSS 3, mean disease duration 7.4 years, median number of previous therapies 3). 106 patients were previously treated with Fingolimod, 80 with Natalizumab, 46 with Dimethylfumarate, 35 were treatment-naïve, 30 with interferon/glatiramer acetate, 10 with Teriflunomide, 9 with other drugs and 6 with Daclizumab. Reason for switch was relapse-rate (41.3%), MRI (22.8%), JCV+ (18.2%), EDSS progression (4.9%), other (12.8%). Median follow-up was 1.94 years. Pre-Alemtuzumab ARR was 0.99, and decreased to 0.13 during Alemtuzumab ($p< 0.001$). Number of previous year relapses was associated with Alemtuzumab-ARR (RR=1.37; $p=0.011$). Washout did not impact on Alemtuzumab-ARR (median 3 months; $p=0.59$). Progression-free survival was 95% after 1 year, and 88.1% after 2 years of Alemtuzumab. EDSS improvement occurred in 13.5% after 1 year, and 23.9% after 2 years. 61.8% of patients achieved NEDA after 1 year and 53.6% after 2 years. 13.9% experienced a relapse between Alemtuzumab courses, and this was linked to higher ARR during the remaining follow-up (RR=4.00; $p< 0.001$). 25 patients dropped-out for adverse events (7), relapse-rate (6), MRI activity (5), compliance (3), other (4).
Conclusions: Alemtuzumab decreases ARR independent of previous therapy, including patients with disease activity during Natalizumab. Relapses between treatment courses are associated with higher disease activity during follow-up.
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